

## PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

To:

FRIEDMAN, Mark, M.  
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ISRAËL

Date of mailing (day/month/year) 08 December 2000 (08.12.00)	<b>IMPORTANT NOTIFICATION</b>
Applicant's or agent's file reference 1934/3	
International application No. PCT/IL00/00553	International filing date (day/month/year) 10 September 2000 (10.09.00)

## 1. The following indications appeared on record concerning:

☒ the applicant    ☐ the inventor    ☐ the agent    ☐ the common representative

Name and Address RAFAEL MEDICAL TECHNOLOGIES INC. c/o Corporate Service Bureau 15 East North Street Dover, DE United States of America	State of Nationality US	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

## 2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person    ☐ the name    ☒ the address    ☐ the nationality    ☐ the residence

Name and Address RAFAEL MEDICAL TECHNOLOGIES INC. c/o Corporate Service Bureau 15 East North Street Dover, DE 19901 United States of America	State of Nationality US	State of Residence US
	Telephone No.	
	Facsimile No.	
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3. Further observations, if necessary:  
ZIP CODE

## 4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input checked="" type="checkbox"/> the International Searching Authority	<input type="checkbox"/> the elected Offices concerned
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Marie-Thérèse Priser Telephone No.: (41-22) 338.83.38
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## PATENT COOPERATION TREATY

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## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
 US Department of Commerce  
 United States Patent and Trademark  
 Office, PCT  
 2011 South Clark Place Room  
 CP2/5C24  
 Arlington, VA 22202  
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 01 June 2001 (01.06.01)	
<b>International application No.</b> PCT/IL00/00553	<b>Applicant's or agent's file reference</b> 1934/3
<b>International filing date (day/month/year)</b> 10 September 2000 (10.09.00)	<b>Priority date (day/month/year)</b> 10 September 1999 (10.09.99)
<b>Applicant</b> BRUCKHEIMER, Elchanan	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

19 March 2001 (19.03.01)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	<b>Authorized officer</b>  Claudio Borton  Telephone No.: (41-22) 338.83.38
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## PATENT COOPERATION TREATY

## PCT

REC'D 24 DEC 2002

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1934/3	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IL00/00553	International filing date (day/month/year) 10 SEPTEMBER 2000	Priority date (day/month/year) 10 SEPTEMBER 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A61M 29/00 and US Cl.: 606/200; 623/1.24		
Applicant RAFAEL MEDICAL TECHNOLOGIES LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).


These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

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MAY 29 2003

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Date of submission of the demand 19 MARCH 2001	Date of completion of this report 31 JULY 2002
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  MICHAEL THALER
Facsimile No. (703) 305-3230	Telephone No. (703) 308-2981

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL00/00553

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☒ the description:  
pages 1-11, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of
- ☒ the claims:  
pages 12-13, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of
- ☒ the drawings:  
pages 1-6, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of
- ☒ the sequence listing part of the description:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig. NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL00/00553

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. statement**

Novelty (N)

Claims	<u>1-13</u>	YES
Claims	<u>NONE</u>	NO

Inventive Step (IS)

Claims	<u>NONE</u>	YES
Claims	<u>1-13</u>	NO

Industrial Applicability (IA)

Claims	<u>1-13</u>	YES
Claims	<u>NONE</u>	NO

**2. citations and explanations (Rule 70.7)**

Claims 1-13 lack an inventive step under PCT Article 33(3) as being obvious over Barbut et al. Barbut et al. show a closed loop 240 (shown in figure 4 and described in col. 13, line 58 to col. 14, line 31) which obviously is straightened to some extent when it is folded up to be stored in the cannula 205.

\_\_\_\_\_ NEW CITATIONS \_\_\_\_\_  
NONE

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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131863 10 September 1999 (10.09.1999) **IL**
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- (54) Agent: **FRIEDMAN, Mark, M.**; Beit Samueloff, Haomanim Street 7, 67897 Tel Aviv (IL).
- (81) Designated States (national): **AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.**
- (84) Designated States (regional): **ARIPO** patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), **Eurasian** patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), **European** patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), **OAPI** patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:**  
— Without international search report and to be republished upon receipt of that report.
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **INTRAVASCULAR DEVICE AND METHOD USING IT**

(57) Abstract: An intravascular device for minimally invasive deployment within a vessel includes a closed loop of flexible material configured to assume a first state in which the closed loop is folded on itself and straightened to allow delivery through a minimally invasive delivery system. When deployed, the loop assumes a second substantially ring-shaped state to become lodged against an inner wall of the vessel. The loop is preferably formed from a shape memory alloy preset to the second state and temporarily deformed to assume said first state during deployment.

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## INTRAVASCULAR DEVICE AND METHOD USING IT

### FIELD AND BACKGROUND OF THE INVENTION

This invention relates to intravascular devices, and to methods of treatment using such devices.

5 Many forms of congenital heart disease result in shunting of the blood from the high resistance left-ventricle-aorta circuit into the low resistance right ventricle pulmonary artery circuit. This blood returns to the heart instead of going to the body and overloads the left ventricle causing congestion. This condition, known as congestive heart failure, is associated with difficulty in breathing and increased  
10 energy expenditure causing failure to thrive in the case of an infant. An additional and no less important aspect of such a shunt is the exposure of the lung blood vessels to high flow rates and pressures which eventually cause irreversible damage.

The solutions to the problems imposed by a large shunt include: medication to reduce the shunt, and repair of the heart defect by surgery or pulmonary artery  
15 banding [PAB]. This latter option, PAB, is employed today in cases when repair of the defect is not possible due to defect type or infant size or as a first stage palliative procedure for complex congenital disease.

PAB involves a surgical procedure under general anesthesia during which the chest is opened and a band of synthetic material is placed around the main  
20 pulmonary artery and tightened relatively arbitrarily to increase the resistance to flow. During the surgery pressures and oxygen saturation can be measured to evaluate the hemodynamic effect of banding however this does not always correlate well with findings after surgery. Apart from the general disadvantages of surgery [wound, scar, possibility of infection], surgical PAB can lead to distortion of the  
25 pulmonary arteries due to band migration. In addition if the band is too tight or loose it cannot be adjusted without additional surgery. Once the band has served its purpose it has to be removed by surgery and the damaged area of the pulmonary artery is repaired. This is usually performed during the repair of the underlying defect.

The fields of cardiac catheterization and angiography have changed immensely with the introduction of transcatheter therapeutic/interventional techniques. It is now possible to close cardiac defects, relieve narrowings of systemic, pulmonary and coronary arteries, occlude accessory vessels, biopsy the heart and open valves through a small entry site, less than 2.5-3mm, in the groin. These procedures obviate the need for surgery, including open heart, while affording excellent results. This minimally invasive approach avoids scarring and affords a more rapid recovery. The transcatheter procedure is usually performed on an overnight or same day basis thereby significantly reducing hospital stay and costs. A common example is the use of stents instead of bypass surgery in coronary artery stenosis.

An additional form of disease amenable to transcatheter therapy is pulmonary embolism. This condition is the result of blood clots which form in a vein of the lower part of the body and break loose, migrating to the lungs. One form of treatment of these emboli is by inserting a filter in a blood vessel such as the vena cava to interrupt the travel of these emboli. One such filter is disclosed in U.S. Patent No. 4,425,908. Devices currently in use require relatively large sheaths for insertion, and are usually irretrievable.

#### SUMMARY OF THE INVENTION

It is an object of the present invention to provide an intravascular device which can be delivered to a desired location by use of a catheter.

It is a further object of the invention to provide a method for treatment of certain intravascular diseases using an intravascular device which can be delivered to a desired location by use of a catheter.

In one aspect of the invention, there is provided an intravascular device for positioning in a blood vessel and capable of being delivered to the blood vessel in a catheter, comprising a platform on which functional structures may be mounted, or with which they may be integrally formed. The platform is preferably composed of a shape memory alloy, such as Nitinol, and is configured to form a collapsed folded



conformation in which it can be straightened for transcatheter delivery, and is further configured to subsequently form an expanded ring conformation. The properties and design considerations for shape memory alloys are now well documented and will not be discussed here in detail.

5           Thus, according to the teachings of the present invention there is provided an intravascular device for minimally invasive deployment within a vessel, the intravascular device comprising a closed loop of flexible material configured to assume a first state in which the closed loop is folded on itself and straightened to allow delivery through a minimally invasive delivery system and, when deployed, assumes a  
10           second substantially ring-shaped state to become lodged against an inner wall of the vessel.

          According to a further feature of the present invention, the closed loop is formed from a shape-memory alloy preset to the second substantially ring-shaped state, the closed loop being subsequently deformed to assume the first state prior to delivery.

15           According to a further feature of the present invention, the substantially ring-shaped state is implemented with a curvature configured such that advancing of the loop in a feed direction from a delivery system results in deployment of the loop in a direction generally perpendicular to the feed direction.

          In the present disclosure, the following terms have the indicated meanings:

20           *platform* – a supporting structure on which functional structures may be mounted, attached or integrally formed. The platform will generally be fixable to the walls of the blood vessel. The platform itself generally does not have a function other than to support other functional structures. Examples of functional structures which may be supported by the platform include, but are not limited to, a pulmonary artery  
25           band for regulating blood flow, a filter for emboli and a valve.

*ring conformation* – a circular band having an internal bore.

*shape memory alloy* – a metal alloy which exhibits shape memory properties, namely, which returns to a predefined shape when exposed to a temperature above a given phase transformation temperature. As is well known for minimally invasive  
30           medical procedures, the shape memory alloy may advantageously be designed to as

to be stored in a deformed state at room temperature while reverting to its predefined shape at body temperature

Shape memory alloys compatible with the device of the invention may be based on various metals such as iron, copper or nickel, as long as they are biocompatible. A preferred shape memory alloy is Nitinol, which is made from nickel and titanium in approximately equiatomic amounts or a slight increase of nickel. A description of Nitinol may be found, *inter alia*, in U.S. Patent No. 4,425,908 whose contents are incorporated herein by reference. Small changes [less than 1%] in the percentage of nickel in the alloy confer large changes in the properties of the alloy, particularly with respect to the transformation temperature. A preferred Nitinol alloy will comprise a weight percentage of 55-56% nickel in order to have shape memory and superelastic properties at body temperature. A most preferred alloy will comprise 55.1-55.6% nickel.

The use of a shape memory alloy imparts to the device the property of retrievability. The latter is of considerable importance in transcatheter implantations of expanding devices since the now expanded device usually makes transcatheter removal unfeasible, even after a short period of time. Complications of implantation, particularly incorrect positioning or migration, may require removal of the device and repositioning. If the device cannot be collapsed down to its original size and reinserted into the delivery sheath, then its removal by a transcatheter method may be impossible and surgery required. This can be avoided by using the device of the invention.

In a preferred embodiment, the platform of the device comprises a breakable section, that is, a portion which allows a gap to be introduced into the continuity of the ring, as will be further exemplified below. This facilitates cancellation of the effect of the device *in situ* by breaking it, in a case where the device is no longer needed.

In another aspect of the invention, there is provided a method for reducing the diameter of a blood vessel comprising:

- (a) inserting into a catheter a intravascular platform as defined above in a collapsed conformation, wherein an inflatable band in an uninflated state is mounted on the platform;

- (b) delivering the device to the blood vessel by introducing the catheter into the blood vessel;
- (c) ejecting the device out of the catheter into the lumen of the blood vessel, whereby the platform assumes an expanded ring conformation; and
- 5 (d) inflating the inflatable band.

In a still further aspect of the invention, there is provided a method for filtering emboli in the blood stream comprising:

- (a) inserting into a catheter a intravascular platform as defined above in a collapsed conformation, wherein a filter is mounted on, or integrally formed with, the platform;
- 10 (b) delivering the device to the blood vessel by introducing the catheter into the blood vessel; and
- (c) ejecting the device out of the catheter into the lumen of the blood vessel, whereby the platform assumes an expanded conformation.

## 15 BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

20 **Fig. 1** is a sectional front view of one embodiment of the device of the invention;

**Fig. 2A** is an enlarged partial view of the platform portion of the device of Fig. 1;

**Figs. 2B, 2C and 2D** are enlarged partial views of portions of the view of Fig. 2A;

25 **Figs. 3A and 3B** are enlarged sectional views of the device of Fig. 1. Fig. 3A is a front view and Fig. 3B is a side view 90° perpendicular to Fig. 3A;

**Fig. 4** is a sectional plan view illustrating another embodiment of the device of the invention in an expanded conformation;

**Fig. 5** shows the embodiment of Fig. 4 in a collapsed conformation;

**Figs. 6A, 6B, 6C and 6D** illustrate a schematic representation of the delivery of the device of the invention to a desired site in a blood vessel;

**Fig. 7** illustrates a further embodiment of the platform of the invention; 7A is before expansion and 7B is after expansion;

5        **Fig. 8** illustrates a still further embodiment of the platform of the invention; 8A is before expansion and 8B is after expansion;

10        **Figs. 9A and 9B** illustrate an implementation of a Nitinol ring particularly effective for achieving transverse deployment of the platform of the present invention relative to a deployment catheter, the ring being shown in a straight state prior to deployment and in its deployed state, respectively;

**Figs. 9C and 9D** are a side view and a front view, respectively, showing the Nitinol ring of Figures 9A and 9B during deployment from a catheter; and

**Fig. 9E** is an enlarged view of a part of the ring of Figure 9B showing an additional optional feature of the present invention.

## 15    DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to Fig. 1, there is illustrated one embodiment of an intravascular device according to the invention, being an intravascular pulmonary artery band, generally designated 2. The device is shown in its expanded conformation, and comprises a ring-shaped platform 4 defining an inner aperture or  
20    bore 5. An inflatable annular band 6 is coaxially mounted on the platform 4 within the aperture 5, the width of the band correspondingly reducing the diameter of the aperture. In this embodiment, the device functions as an internal transcatheter pulmonary artery band for use in the treatment of congestive heart failure due to congenital heart disease. The ring fixes the band into place by exerting pressure on  
25    the inner pulmonary artery wall.

The platform portion of the device is in a ring shape in the expanded conformation. The dimensions of the ring may easily be determined by the skilled man of the art, depending on the dimensions of the blood vessel to be occluded, for example by biplane angiography. Preferably, the ring diameter will be approximately

2 mm larger than the native pulmonary artery internal diameter. For example, if the artery diameter is 8 mm, the ring diameter will be 10mm. Each additional size may be 2mm larger, e.g. 12mm, 14mm, 16mm etc, to accommodate for larger pulmonary artery diameters.

5           The platform 4 is composed of a shape memory alloy such as, e.g. Nitinol. The structure of the platform may be composed of one or more strands of Nitinol of varying diameters. One example of the structure of the ring is shown in Fig. 2A, which illustrates one thick 8 and two thin 10 Nitinol strands interwoven into a lattice. In many cases, slight oversizing of the ring structure is sufficient to retain the device  
10 in place. The thicker strand may optionally attach to the inner wall of the pulmonary artery by having a serrated, bumpy edge 12 (Fig. 2B). Additionally, or alternatively, further retention may optionally be provided by provision of several small hooks 14 (Fig. 2C) which penetrate the inner lining of the artery. Deep penetration of the artery wall by the hooks is prevented by the adjacent loops 16 of the Nitinol strand  
15 which "cushion" the band against the arterial wall (Fig. 2D).

          The band 6 may be composed of any flexible material which does not interact with the blood. To form an adjustable band, balloons may be attached to the Nitinol ring. These balloons will preferably be composed of an inert, biocompatible material such as silicon. The attachment of the band to the platform is illustrated in Fig. 3. In  
20 a preferred embodiment, the platform becomes part of the silicone balloon on its lateral aspect by having the balloon "melted" on during device manufacture.

          The band may be comprised of one or more coupled inflatable balloons. Figs. 4 and 5 illustrate one embodiment of the invention in which the device 18 comprises a band 20, consisting of two linked sausage-shaped balloons 22 & 24, mounted on a  
25 platform 26. The balloons are expanded by pushing fluid into them via a feeding catheter 28 which feeds the balloons through an elastic collar 30 which is attached to the balloons. The fluid may be isotonic saline at body temperature or a colloid at higher osmotic pressure so that fluid will not seep out. Preferably, the fluid is saline.

          The collar is held open by a reinforced end region of the feeding catheter  
30 which extends through an aperture in the center of the collar. The balloons are joined

by a connector 32 which may open at a predetermined pressure [e.g. 1-2 atms] to allow for the second balloon to be expanded, if required. The balloons may also be concentrically positioned within the platform (see Fig. 6D). Thus, the diameter of the band may be adjusted, depending on the hemodynamic status of the blood vessel.

- 5 The decision whether to further expand or reduce the size of the balloons [by feeding or withdrawing fluid] is determined by hemodynamic measurements taken during band implantation. In order to insert the device in a catheter, the device is collapsed into its folded conformation (Fig. 5), with the band in an uninflated state.

The delivery of the illustrated embodiment of the device to a desired location  
10 in a blood vessel is exemplified in Figs. 6A-D. The device 34 is maintained in a collapsed conformation while in the delivery catheter 36. The delivery catheter contains within it a feeding catheter 38 enveloped by a release catheter 40. The delivery catheter is advanced in the artery 41 to the desired location in the blood vessel, at which the device 34 is extruded into the arterial lumen 42 (Fig. 6A). As the  
15 device 34 is advanced out of the catheter, the platform 44 expands to its preformed shape within the lumen 42 and attaches to the inner wall 46 of the artery (Fig 6B). Once the ring is in its optimal position, the band is inflated through the feeding catheter.

The preformed shape of the ring is such that a ring is formed at a right angle  
20 to the axis of the delivery catheter (Fig. 6C). For example, the connection between the Nitinol ring and delivery system may be given a preformed shape of 90°. Alternatively, the delivery catheter may be angled at its end so that the ring protrudes at an angle when advanced out of the catheter.

Figures 9A-9E show a particularly preferred configuration of the Nitinol ring  
25 itself for implementing the aforementioned 90° turn on deployment of the platform 44. Specifically, the shape memory material is here preset to a form resembling an open pair of jaws (Figure 9B) exhibiting a roughly circular form in plan view while having roughly a C-shaped form in side view (Figure 9C). The C-shaped curvature ensures the required transverse deployment as the device is gradually released from  
30 the delivery catheter 36 (Figures 9C and 9D).

Optionally, the structure illustrated in Figures 9A-9E may be implemented using an appropriately shape-set closed loop of Nitinol wire. Alternatively, in the preferred implementation as shown, the structure may be constructed from a single rod of Nitinol which is subdivided by a slit 60 running along a major part of its length but stopping short of its ends. This results in two separable lobes, each of roughly semicircular cross-section. Optionally, a torsional deformation may be included in the preset shape to ensure that the smoothly curved outer surface of each lobe faces outwards towards the vessel wall, thereby spreading loading. According to a further option, the semicircular-cross-section lobes may themselves be subdivided by small slits 62 and biased to open up into a latticework-type form (Figure 9E) to further spread loading of the vessel wall.

If necessary, the feeding catheter may be left in place so that additional adjustments in the band diameter may be made. Once the dimensions of the device are finally established, the feeding catheter is pulled free from the collar which seals the fluid in the band. The device may be released from the catheter by advancing the release catheter 40 against the collar 48 while pulling back on the feeding catheter 38, thereby pushing the collar off the feeding catheter. The elastic collar then closes and the detached device (Fig. 6D) is implanted in the arterial wall. Other release mechanisms are of course possible, as will be clear to the skilled man of the art. For example, release of the ring independent of the feeding catheter may be achieved by having an attachment wire coaxial to the feeding catheter which can either unhook or unscrew from the ring.

In some cases, it is desirable to remove the device after a certain period of time. As stated above, prior art devices generally require surgery in order to remove them. The device of the invention, however, can be made 'breakable' or capable of being severed so that the band can be released in the same way in which it was inserted, i.e. by a transcatheter technique.

The connector is the weak link of the device which allows for the platform to be broken when it is no longer required. This can be achieved by passing a high pressure balloon catheter through the lumen in the center of the band and expanding

the balloon. The ring will be breached due to the presence of a breakable section, and the fluid will leak out of the torn apart balloons. The Nitinol ring and silicone may then become part of the pulmonary arterial wall and become covered by endothelium (the inner lining). Or alternatively the band can be removed by a definitive surgical procedure.

In order for the Nitinol ring to be 'breakable', a weak link may be created in the platform. One example is illustrated in Fig. 7. A thick Nitinol strand 50 is folded for a small distance creating an area 52 which can be unfolded and expanded 54 at a later stage during a catheterization procedure, by advancing a high pressure balloon of a larger diameter than the platform through the lumen of the band and expanding the balloon to the desired diameter.

An alternative approach is illustrated in Fig. 8. The ends 56 of the thick Nitinol strand meet inside a stiff sleeve 58 in which they overlap but are not connected. The sleeve provides support for the broken platform by not allowing the platform to collapse or fold in on itself. However when the platform is expanded by a high pressure balloon, the ends of the Nitinol strand come apart. The balloons are broken at the connector.

A further embodiment of the device of the invention is a vena cava filter for pulmonary emboli. The device of the invention would comprise a platform as described above and a filter. The filter may be made of crosslinks of Nitinol wire attached to the filter and since these are made of shape memory alloy they can be folded easily into the delivery catheter. The fixation of the platform *in situ* would be by diffuse pressure of the ring on the vessel wall, preventing deep penetration of the hooks as described above with respect to the pulmonary band.

A still further embodiment using a platform of the invention could include a form of transcatheter cardiac or vessel valve. Examples of valves which could be mounted on the platform are pericardial valves, bovine, pig, etc. or synthetic material.



Although several preferred embodiments have been described above, the scope of the invention is defined by the following claims.

## WHAT IS CLAIMED IS:

1. An intravascular device for minimally invasive deployment within a vessel, the intravascular device comprising:

a closed loop of flexible material configured to assume a first state in which said closed loop is folded on itself and straightened to allow delivery through a minimally invasive delivery system and, when deployed, assumes a second substantially ring-shaped state to become lodged against an inner wall of the vessel.

2. The intravascular device of claim 1, wherein said closed loop is formed from a shape-memory alloy preset to said second substantially ring-shaped state, said closed loop being subsequently deformed to assume said first state prior to delivery.

3. The intravascular device of claim 2, wherein said alloy is Nitinol.

4. The intravascular device of claim 1, wherein said substantially ring-shaped state is implemented with a curvature configured such that advancing of said loop in a feed direction from a delivery system results in deployment of said loop in a direction generally perpendicular to said feed direction.

5. The intravascular device of claim 1, further comprising an inflatable device mechanically linked to said ring.

6. The intravascular device of claim 1, further comprising an intravascular filter structure mechanically linked to, or integrally formed with, said ring.

7. The intravascular device of claim 1, further comprising a valve member mechanically linked to said ring.

8. The intravascular device of claim 1, wherein said closed ring includes a breakable section.

9. The intravascular device of claim 1, wherein a band is mounted on said closed ring.
10. The intravascular device of claim 9, wherein said band includes at least one inflatable balloon.
11. The intravascular device of claim 10, wherein said balloons are made of silicone.
12. The intravascular device of claim 9, wherein the diameter of said band is adjustable.
13. The intravascular device of claim 9, wherein said band is a pulmonary artery band.

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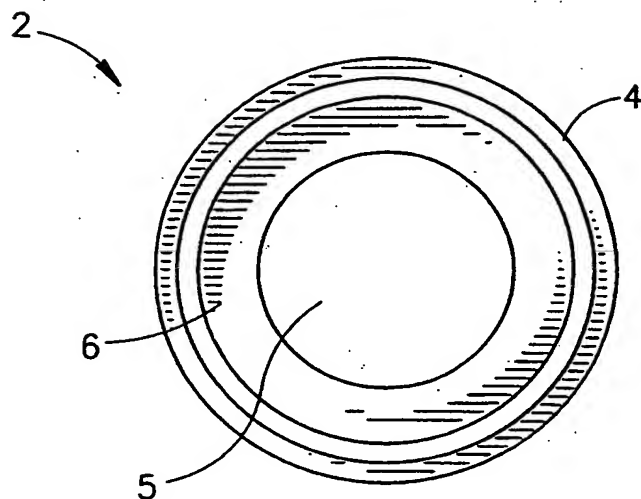


FIG. 1

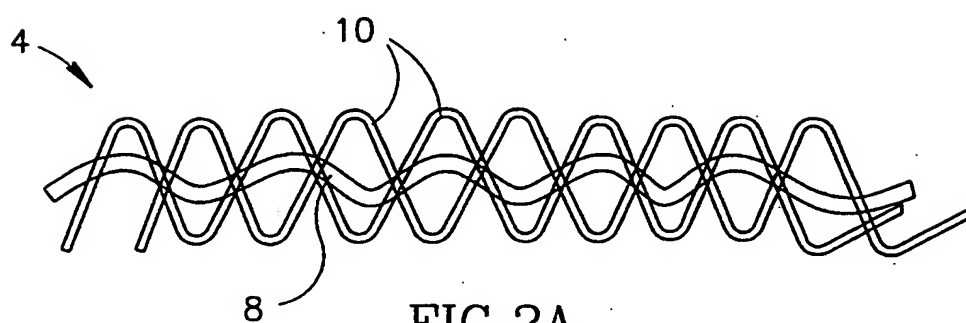


FIG. 2A



FIG. 2B

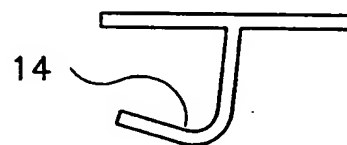


FIG. 2C

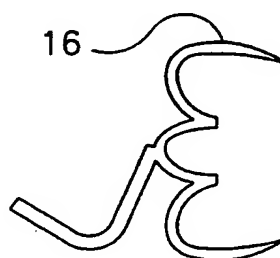


FIG. 2D

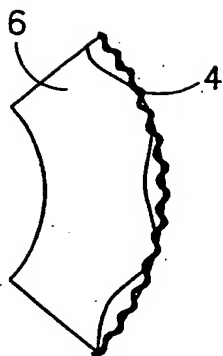


FIG. 3A

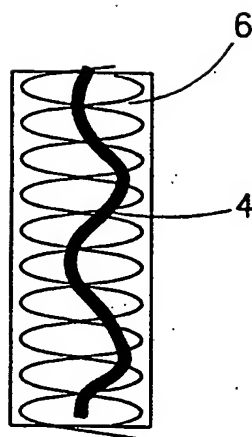


FIG. 3B

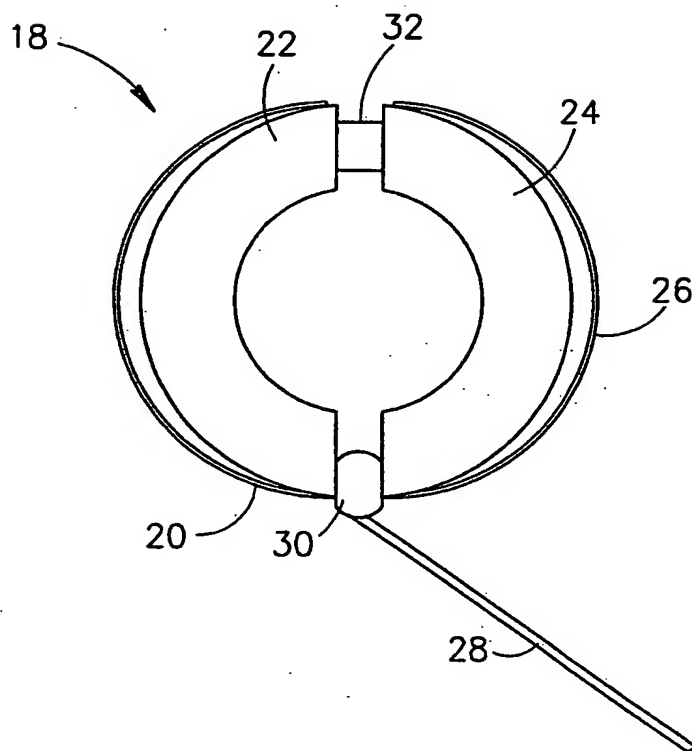


FIG. 4

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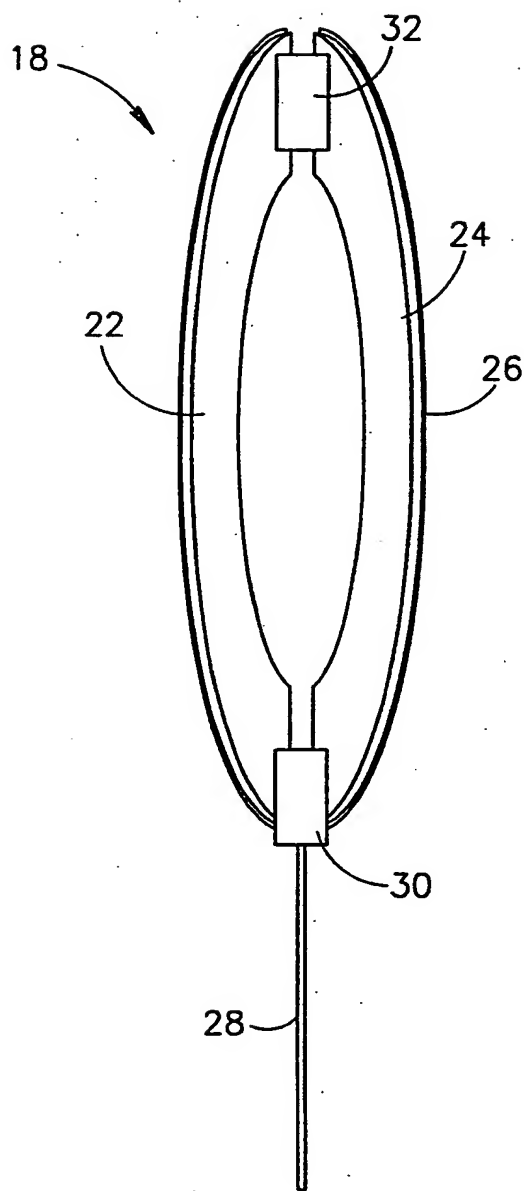


FIG. 5

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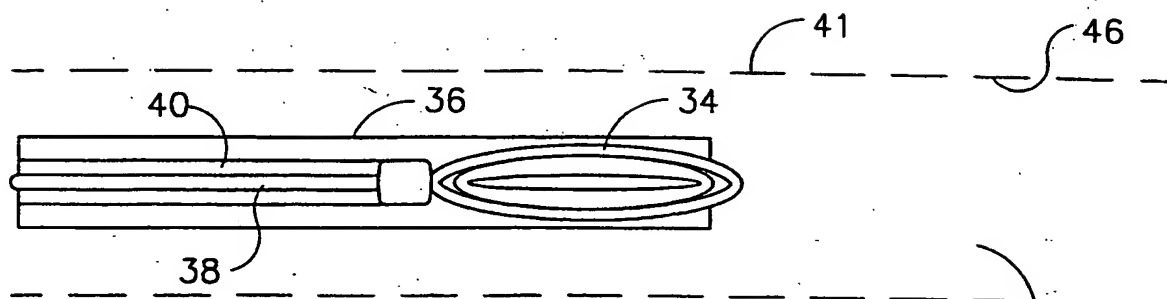


FIG. 6A

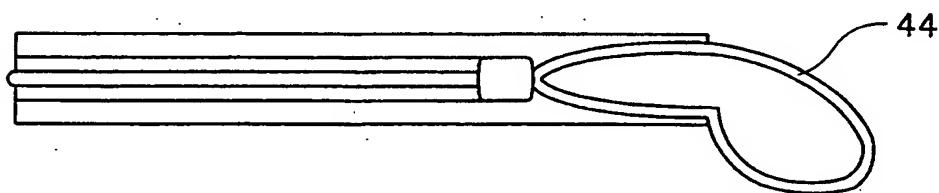


FIG. 6B

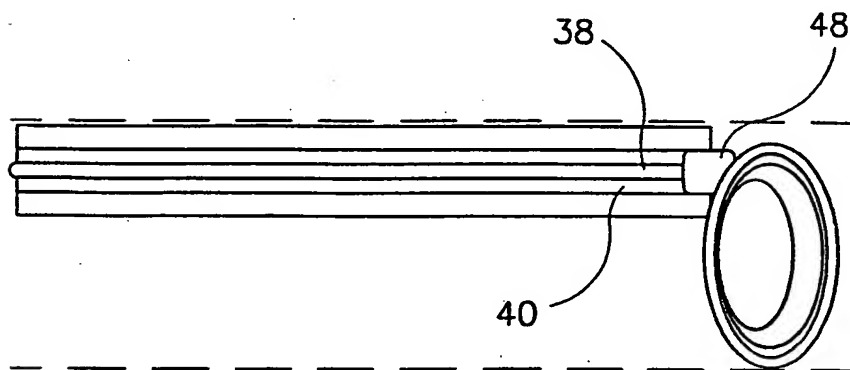


FIG. 6C

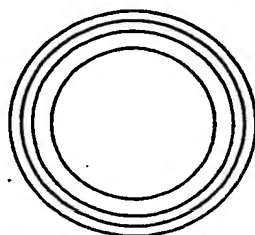


FIG. 6D

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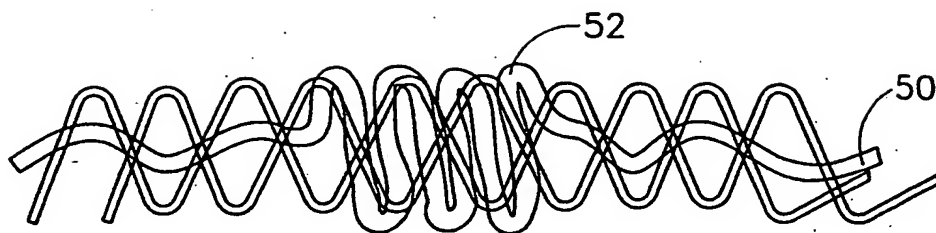


FIG. 7A

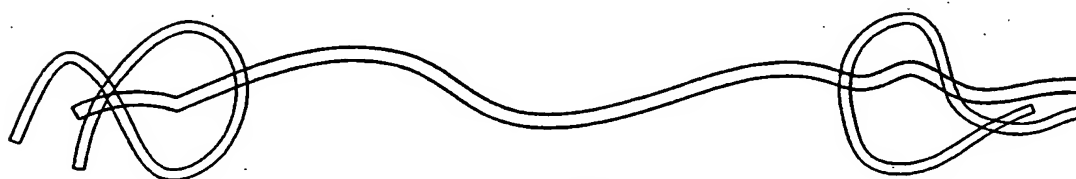


FIG. 7B

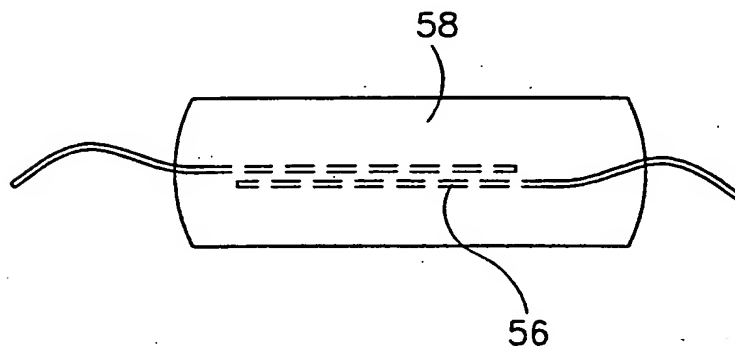


FIG. 8A

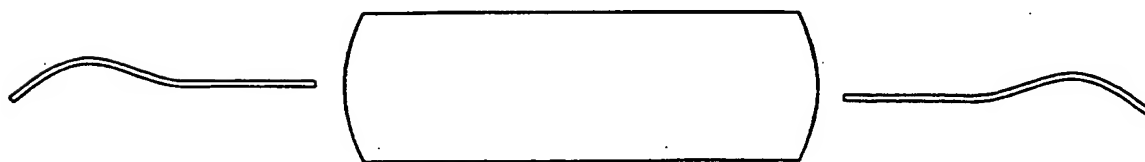
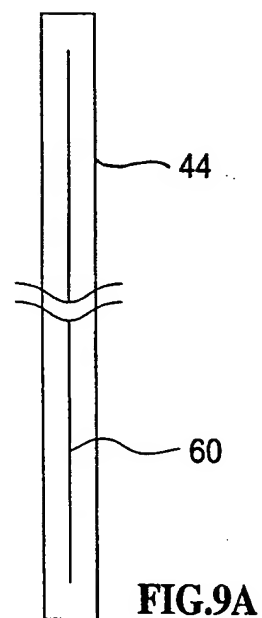
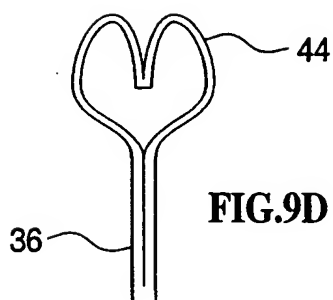
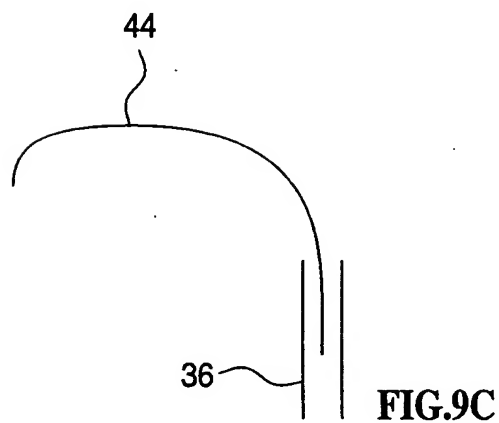
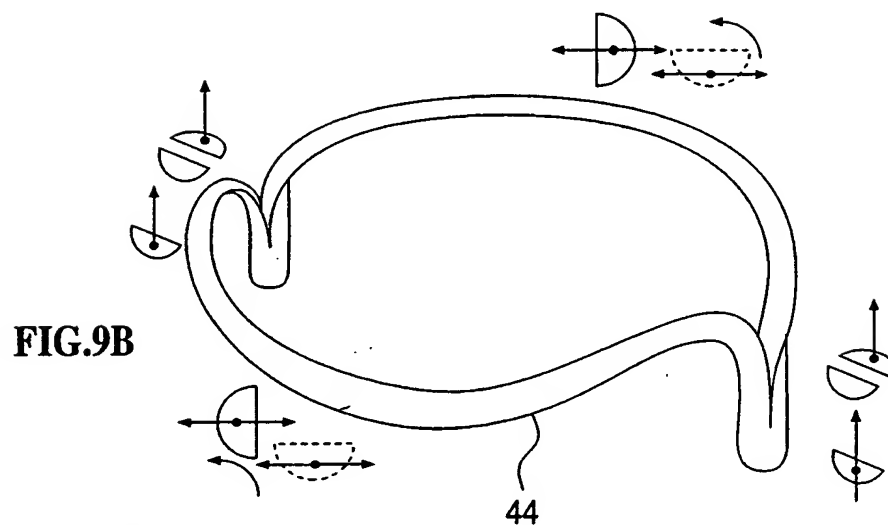
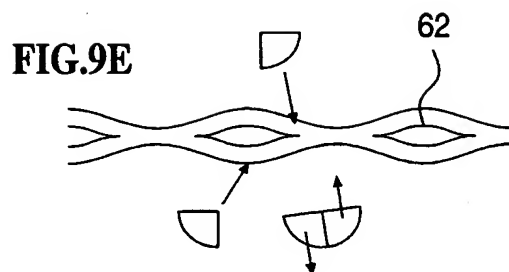


FIG. 8B





**FIG.1 (PRIOR ART)**

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(10) International Publication Number  
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10 September 2000 (10.09.2000)

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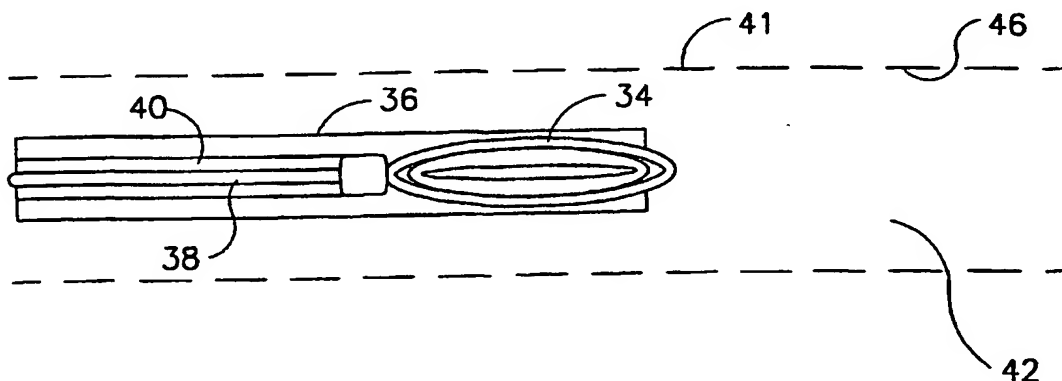
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **INTRAVASCULAR DEVICE AND METHOD USING IT**



(57) Abstract: An intravascular device (34) for minimally invasive deployment within a vessel includes a closed loop (4) of flexible material configured to assume a first state in which the closed loop is folded on itself and straightened to allow delivery through a minimally invasive delivery system. When deployed, the loop (4) assumes a second substantially ring-shaped state to become lodged against an inner wall (46) of the vessel. The loop (4) is preferably formed from a shape memory alloy preset to the second state and temporarily deformed to assume said first state during deployment.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IL00/00553

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61M 29/00

US CL :606/200; 623/1.24

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/200; 623/1.24, 1.25, 1.26, 1.2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,769,816 A (BARBUT ET AL.) 23 JUNE 1998, COL. 13, LINE 58 TO COL. 14, LINE 31.	1-13
A	US 5,423,851 A (SAMUELS) 13 JUNE 1995, SEE ENTIRE DOCUMENT.	1-13
A	US 5,053,008 A (BAJAJ) 01 OCTOBER 1991, SEE ENTIRE DOCUMENT.	1-13

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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